IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, *et al.* Defendants.	Civil Action No. 3:17-01362
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, *et al.* Defendants.	Civil Action No. 3:17-01665

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF ANDREW KOLODNY

Plaintiffs offer Dr. Andrew Kolodny, a specialist in addiction medicine, to testify about nearly every aspect of their case, including Defendants' alleged bad acts, legal opinions about Defendants' regulatory obligations and the existence of a public nuisance, the treatment of chronic pain, and programs to abate the purported nuisance. Yet Dr. Kolodny is not an expert in the vast majority of those areas, and is serving in effect as a "talking brief" to advance opinions on points far afield from his area of expertise in addiction medicine. Nor would it be helpful for even a qualified expert to present internal emails, DEA administrative actions, and media stories to the Court by armchair interpretations based solely on the face of the documents. The Court does not need an expert to make credibility determinations about Defendants or any of their witnesses, to

define legal terms of art, or to apply legal standards to the facts of the case. Dr. Kolodny's testimony should accordingly be confined to the subject of his legitimate expertise, and he should not be permitted to offer opinions on subjects clearly outside that expertise.

I. Background

Dr. Kolodny is a medical doctor who specializes in addiction medicine, psychiatry, and neurology, including the treatment of opioid use disorder. Ex. 1, Expert Report of Andrew Kolodny ("Report") at 3. He currently serves as Medical Director for the Opioid Policy Research Collaborative at Brandeis University in New York. *Id.* He has previously held positions in public health, including with the New York City Department of Health and Mental Hygiene. *Id.* at 4.

In addition to his core opinions on addiction and medical standard-of-care, Dr. Kolodny's expert report offers a wide range of subject matter, encompassing almost every contested issue of fact and law in this case, including:

- The definition and existence of a public nuisance in Huntington and Cabell County (Ex. 1, Report at 1);
- The history and origin of the opioid epidemic in the United States, including alleged harms that have stemmed from opioid abuse (*id.* at 10, 18);
- Criminal drug activity including the trafficking of diverted prescription pills and patterns of illicit drug use (*id.* at 31, 35);
- Descriptions and determinations regarding the conduct of non-party pharmaceutical manufacturers (*id.* at 37, 66);
- Descriptions of the business activities of Defendants in this case, including promotional activities, compensation structures, supply chain management, and distribution (*id.* at 27, 40, 48, 70, 75);
- Individual alleged bad actors in Huntington, including specific doctors and pharmacies (*id.* at 53, 58);
- Descriptions of Defendants' regulatory compliance programs and other internal documents (*id.* at 62);
- Descriptions of the relationship and communications between Defendants and the DEA, including determinations about Defendants' regulatory compliance (*id.* at 64, 78);
- Descriptions of Defendants' and other group's public statements and interactions with policymakers (*id.* at 84, 88, 95, 102);
- Actions the federal government has taken at a national level to respond to the opioid crisis (*id.* at 98);

- Discussion of ultimate responsibility and foreseeability regarding opioid-related harm (*id.* at 105–106)
- Abatement strategies for the opioid crisis (*id.* at 107).

According to Dr. Kolodny, this may not be an exhaustive list of his testimony at trial, as it is "possible" that he intends to offer opinions not included in his report. Ex. 2, Kolodny Dep., Sept. 4, 2020 ("Dep.") at 11:18–22.

II. Argument

In order to render an admissible expert opinion under Rule 702, an expert must have "scientific, technical, or other specialized knowledge" to "help the trier of fact" and must use reliable principles and methods to arrive at his opinion. Fed. R. Evid. 702. *See also Koger v. Norfolk S. Ry. Co.*, No. CIV.A. 1:08-0909, 2010 WL 692842, at *1 (S.D.W. Va. Feb. 23, 2010) (J. Faber) ("Helpfulness to the trier of fact is the touchstone of Rule 702.").

Dr. Kolodny is a doctor whose specialty is treating addiction. While that qualification may permit him to render some opinions related to addiction—assuming that those opinions meet the other *Daubert* factors—it does not grant him broad authority to testify on subjects outside his areas of expertise or specialized knowledge. *See Free v. Bondo-Mar-Hyde Corp.*, 25 F. App'x 170 (4th Cir. 2002) (affirming the exclusion of testimony because highly credentialed expert nevertheless lacked knowledge of specific matters essential to subject of his opinion); *Rheinfrank v. Abbott Labs.*, Inc., 680 F. App'x 369, 380 (6th Cir. 2017) (affirming exclusion of testimony on regulatory issues by neurologist, geneticist, and epidemiologist, and noting that "several other courts have similarly limited the testimony of medical experts to questions within their specialized medical ken"); *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 697–98 (W.D.N.C. 2003) (barring physicians' purported expert testimony because "any expert, including physicians, must have the specialized knowledge or skill in the specific area in which the testimony is proffered").

Furthermore, many of the areas in which Dr. Kolodny proffers opinions are based on what he has learned since being retained as a plaintiffs' expert in the opioid litigation. Dr. Kolodny testified that he had not "really stud[ied] the role that distributors played in the crisis" until he became involved in this litigation. Ex. 3, Kolodny Dep., July 21, 2020 ("OHAG Dep.") at 33:8–15, 34:15–36:9.[1] He now offers opinions on certain of distributors' business practices—like promotional activities—but he did not learn about those practices until after February 2020. *Id.* at 31:8–20. And he now offers opinions on distributors' suspicious order monitoring systems, but he has never been involved in these issues outside his role as an expert in this litigation. Ex. 2, Dep. at 174:17–21. Knowledge gained purely for the purpose of litigation is not sufficient to qualify a witness as an expert. *See Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (holding that a "very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.").

Specifically, although Defendants acknowledge that some opinions regarding addiction may be within the scope of Dr. Kolodny's qualifications, the following five topics on which he purports to offer opinions are well outside his area of expertise and should be excluded.[2]

[1] Dr. Kolodny also serves as an expert for plaintiffs in the Ohio Attorney General's suit against distributors and gave a deposition in that matter on July 21, 2020, shortly before his August 3 report was provided in this case.

[2] In addition to the five topics listed here, Dr. Kolodny (in addition to other Plaintiffs' experts) also offers opinions regarding Defendants' alleged marketing activities, as well as opinions on corporate conduct and his views on their proper role as corporate citizens. Defendants have filed separate *Daubert* motions to preclude such testimony by Plaintiffs' experts, including Dr. Kolodny.

1. Opinions Stating Legal Conclusions and Legal Standards

The first page of Dr. Kolodny's report says that he was asked to opine on "whether Defendants' conduct was a substantial factor in causing a public nuisance in the Cabell-Huntington Communities." Ex. 1, Report at 1. It then provides "legal definitions" for public nuisance, which he received from Plaintiffs' attorneys (ex. 2, Dep. at 219:7–9), that quote from the Restatement (Second) of Torts. Ex. 1, Report at 1.

Dr. Kolodny further offers the following summary opinion about the purported cause of problems related to opioids:

> The conduct of the Defendants, working individually and together, was a substantial factor in causing the Opioid Epidemic. Working closely and in an intertwined and interlinked system with their business partners in the supply chain (namely the opioid manufacturers and chain pharmacies) **without reasonable care**, their **abnormally dangerous behavior** and **blatant violations of the laws and regulations** combined to cause the Opioid Epidemic we see today.

Ex. 1, Report at 105 (emphases added).

"Opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). Courts identify improper legal conclusions by "determining whether the terms used by the witness have separate, distinct and specialized meaning in the law different from that present in the vernacular." *Id.* (citing *U.S. v. Barile*, 286 F.3d 749, 760 (4th Cir. 2002)). Examples of such legal terms include "extortion," "deadly force," "fiduciary," and "unreasonably dangerous." *Id.* "Public nuisance," drawn directly from the Restatement of Torts, as well as "reasonable care" and "abnormally dangerous behavior," fall into the category of impermissible legal terminology. Nor is an addiction treatment specialist like Dr. Kolodny qualified to testify concerning "blatant violations of the laws and regulations." These questions are for the Court to decide. Dr. Kolodny's

opinions on legal standards and legal issues are far outside the expertise of a doctor specializing in addiction treatment.

2. Opinions Based on Dr. Kolodny's "Prudent Distributor" Standard

Dr. Kolodny offers his opinions about what a "prudent distributor" of medicines should have done:

- "***Prudent distributors*** of narcotics drugs would not have participated in a campaign to increase the supply of opioids, as Defendants did." Ex. 1, Report at 105 (all emphases added unless otherwise noted).
- "***Prudent distributors*** of narcotics would not have repeatedly shipped narcotics to corrupt pharmacies, as the Defendants did." *Id.* at 105.
- "***Prudent distributors*** would not have ignored clear evidence that the opioids they were shipping were fueling a public health catastrophe and destroying communities and families across the country, as the Defendants did." *Id.* at 105.
- "***Prudent distributors*** of narcotics would not have participated in a campaign to deceive policymakers and the public about the adequacy of their monitoring systems or mis-framed the opioid crisis to preserve the status quo that was benefitting them financially." *Id.* at 106.

Asked where he got his "standard on prudent distributors," Dr. Kolodny testified that "I don't think you need to take a class or go to -- or earn a degree on what a prudent distributor of narcotics should do." Ex. 2, Dep. at 241:2–7. Thus, as he effectively conceded, Dr. Kolodny does not have any "scientific, technical, or other specialized knowledge" that would "help the trier of fact," Fed. R. Evid. 702, in evaluating what a "prudent distributor" should have done.

Crucially, missing from both Dr. Kolodny's report and his deposition is any basis for his conclusions about what "prudent distributors" would do, a demonstrable failure to meet the standards of *Daubert*. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013) ("Strikingly absent from this discussion is any basis for [proposed expert] Dr. Shull's opinion of what [Defendant] Bard 'should have' done. This is likely the result of Dr. Shull's lack of expertise in the specific area of warnings and labels for medical devices.").

Beyond the fact that the standards of a "prudent distributor" are outside his expertise, and that he failed to provide any basis for those standards, Dr. Kolodny's testimony that "I don't think you need to take a class . . . or earn a degree on what a prudent distributor of narcotics should do" reflects that his opinions on this issue are unscientific, personal opinions that cannot be tested for reliability, and should be excluded on that basis alone. *Bard*, 948 F. Supp. 2d at 604–05 ("Dr. Zolnoun's first general causation opinion is therefore based on nothing more than her personal, unscientific observation and opinion that 'it's obvious' that mesh arms are sharp and can serrate or tear nerves. This is the type of 'subjective, conclusory approach that cannot reasonably be assessed for reliability' and that Rule 702 is designed to exclude.") And the lack of an ***objective standard*** for what a hypothetical "prudent distributor" should do means that the proposed testimony cannot be found to be "anything more than a personal belief or opinion." *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *5 (S.D.W. Va. July 8, 2011).

This Court has previously excluded expert testimony of a similar type, when the proposed expert "could not identify an established, objective industry standard by which to judge the defendants' conduct." *Id.* at *6; *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.").

3. Opinions Regarding Suspicious Order Monitoring or the Regulatory Duties of Distributors

Dr. Kolodny's proposed testimony includes multiple statements about Defendants' regulatory duties, including that "Defendants' systems to evaluate and prevent diversion were demonstrably inadequate. It is clear that the Defendants failed in their obligation as DEA

registrants." Ex. 1, Report at 59. Dr. Kolodny is not qualified to opine on defendant distributors' regulatory duties, including (1) the proper interpretation of the Controlled Substances Act and its implementing regulations, (2) the proper operation of a suspicious order monitoring system, (3) any other obligation distributors have to guard against diversion, or (4) if and how Defendants' regulatory programs impacted the opioid crisis.

In addition to his general lack of familiarity with distributors, Dr. Kolodny admits that he is "not an expert on the specifics of the Controlled Substances Act with regard to distributor obligations." Ex. 3, OHAG Dep. at 76:16–18. He admits he does not have expertise on "the details of the law, the details of how [distributors] failed in their obligations as DEA registrants . . . ." *Id.* at 73:19–25. Prior to his work in this litigation, he had never "reviewed any federal statutes or regulations governing or relating to wholesale distributors and controlled substances." *Id.* at 72:11–16. Outside of what he has learned in this litigation, he did not know what "specific systems" distributors had in place from 1996 to present. *Id.* at 88:18–89:3. His "reasonable understanding" of what was "technically possible" is based on "logic." *Id.* at 89:4–7. Dr. Kolodny has only read "parts of" the suspicious order regulation, of which he has a "basic understanding." *Id.* at 81:3–19.

In short, Dr. Kolodny is offering opinions on suspicious order monitoring systems and regulatory requirements that are far outside his expertise as a doctor. His own testimony confirms this.

4. Opinions Regarding Industry "Front Groups," Public Relations, Lobbying or Legislative Government Relations & Lobbying

Dr. Kolodny purports to offer opinions concerning what he terms industry "front groups" that were intended, in his view, to "influence the medical community, the public, regulators, professional governing bodies and standards organizations." Ex. 1, Report at 16. He purports to

describe "industry groups that promoted misinformation." *Id.* at 49. He claims that the "opioid industry" coordinated to "misinform policymakers." *Id.* at 50. He describes what he terms a "massive campaign to dismantle rules, regulations and government control designed to check supply." *Id.* at 94. He provides his views on industry lobbying activity related to the "Marino Bill," dealing with legislation before Congress involving the Controlled Substances Act. *Id.* at 94–98. He provides his views on regulatory lobbing before the FDA related to controlled substances. *Id.* at 98–100. He offers his views on regulatory lobbing before the CDC involving guidelines for the prescribing of opioids. *Id.* at 100–01.

Dr. Kolodny has no "specialized expertise," Fed. R. Evid. 702, in any of these areas. He is simply reading documents and offering his personal viewpoints. That is not a proper function of expert testimony. In particular, he admitted that "he maybe had a little bit of experience with lobbying for legislation, but not much." Ex. 2, Dep. at 228:8–12. His purported knowledge of the Pain Care Forum, which Dr. Kolodny describes as an industry "front group," is based on "one meeting with them" (*id.* at 230:4–8), along with investigative journalism, informal conversations, and materials produced in discovery that he has read.

It is not a proper function of expert testimony for a witness to read documents in a field outside his area of expertise and then to recite his viewpoints. *Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 2:10-CV-00837, 2012 WL 524442, at *8 (S.D.W. Va. Feb. 15, 2012) (excluding expert's opinion that was not based on his experience or education, but rather was based on other experts' testimony and the defendant's corporate documents). Dr. Kolodny, an addiction treatment doctor, has no "specialized knowledge" related to legislative or regulatory activities, industry lobbying groups, and the activities of trade organizations. He is simply collating facts and reciting them, in a field entirely outside his expertise. This is not permissible expert testimony. *Hines v.*

Wyeth, No. 2:04-0690, 2011 WL 2680842, at *5 (S.D.W. Va. July 8, 2011) (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness").

5. Opinions as to the Credibility of Defendants or Other Witnesses

It is universally accepted that experts may not testify to credibility. *U.S. v. Dorsey*, 45 F.3d 809, 815 (4th Cir. 1995) ("[E]xpert testimony can be properly excluded if it is introduced merely to cast doubt on the credibility of other eyewitnesses, since the evaluation of a witness's credibility is a determination usually within the jury's exclusive purview."). The Tenth Circuit has similarly held that "the credibility of another is not an appropriate subject for expert opinion testimony," adding that "our sibling circuits that have considered this issue have uniformly agreed." *U.S. v. Hill*, 749 F.3d 1250, 1260 (10th Cir. 2014) (citing cases from the First, Second, Fourth, Seventh, Eighth, Ninth and Eleventh Circuits.).

Despite its plain inadmissibility, Dr. Kolodny advanced the claim in his report and in his deposition that McKesson's CEO "perjure[d] himself" by "lying before Congress" in describing McKesson's limited role in marketing prescription opioids or any other specific category of medications. Ex. 2, Dep. at 182:6–18; 183:8–15. Dr. Kolodny then drew from his criticisms of McKesson's CEO to argue, without basis, that *any* statement by McKesson employees is either false or questionable, stating that "the defendants in this case claim that they have fixed their broken systems. I don't know if they can be trusted or not." *Id.* at 182:15–18. In addition to the fact that these opinions do not call for expert testimony and fall well outside of Dr. Kolodny's expertise, they also represent inadmissible credibility determinations regarding Defendants in this case. Such testimony should be excluded as the Court as trier of fact can "make its own determination of credibility." *Hill*, 749 F.3d at 1261.

III. Conclusion

For the reasons above, Defendants request that the Court exclude from Dr. Kolodny's testimony the following opinions:

1. Opinions stating legal standards or legal conclusions.
2. Opinions based on a "prudent distributor" standard.
3. Opinions related to suspicious order monitoring or regulatory compliance.
4. Opinions related to lobbying.
5. Opinions seeking to make credibility determinations of Defendants or other individuals.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 2nd day of October, 2020, the foregoing **Memorandum of Law in Support of Defendants' Motion to Exclude the Expert Testimony of Andrew Kolodny** was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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